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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MACNEILL, ELIZABETH

ART UNIT

PAPER NUMBER

3767

DATE MAILED: 08/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/712,734

Applicant(s)

HUNTER ET AL

Examiner

Elizabeth R. MacNeill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2006.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-39 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 29 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/7/2004;12/1/2003.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, Claims 1-39 in the reply filed on 8 June 2006 is acknowledged. The traversal is on the ground(s) that Groups I and II are directed to overlapping subject matter. This is not found persuasive because the groups are classified in different subclasses, requiring a burdensome search.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 18,19,22, and 26 recite the limitation "the flexure" in reference to claim 1.

There is insufficient antecedent basis for this limitation in the claim.

Claim Objections

3. Claims 37-39 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to multiple claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims 37-39 have not been further treated on the merits.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims are rejected under 35 U.S.C. 102(b) as being anticipated by CROCKER (US #6,890,319).

Regarding claim 1, Crocker teaches a "A medicament delivery system comprising: a reservoir (Col 3 line 59, not shown) for storing medicament, a channel (Col 3 line 59) for carrying a volume of the medicament from the reservoir into a passage within a perforator (1, Figs 2A-2D), and an actuator (2) coupled to the perforator and capable of applying a decelerating force thereto for causing the inertia of the volume to eject the medicament from the hollow perforator (Col 2 lines 27-37)."

Regarding claim 2, the flexure is a leaf spring 4.

Regarding claim 3, the actuator comprises a magnetic coil (solenoid, 8)

Regarding claim 4, there is a housing having an aperture therein (30)

Regarding claim 5, there is a bulge area surrounding the aperture (Fig 6A, 6B)

Regarding claims 6 and 11, the Examiner takes the listing of materials "glass, polymer, metal, ceramic, and composite" as being extensive of any possible material, therefore Crocker rejects it.

Regarding claim 7, the bulge area is configured to stretch the skin (42, Col 9 line 8)

Regarding claim 8, the bulge comprises a circular ridge (Figs 6A and 6B)

Regarding claim 14, the needle (perforator) is a microtube (Col 2 line 63)

Regarding claim 15, the microneedle has a diameter of 10 to 1000 microns (Col 2 line 63), therefore the volume of the microneedle is about 0.5 nanoliters to about 10

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microliters. (Taking the length of the needle to be 200 micrometers, the volume of a 300 micron diameter tube is at most 0.056 microliters)

Regarding claim 16, Crocker discloses that the needles can penetrate 10 microns upwards (Col 2 line 67)

Regarding claim 17, the perforator has an orifice of about 20 to about 800 micrometers. (See Figs 2A-2B, taking the diameter of the microtube to be 10-1000 microns)

Regarding claim 20, there is a plurality of perforators (Fig 5)

Regarding claims 23-25, Crocker teaches the use of an impedance sensor for determining the position of the perforator or the device along the surface of the skin. Col 6 lines 7-15.

Regarding claim 27, the reservoir is connected to the perforator by a length of flexible tubing (Col 3 line 59)

Regarding claim 28, the medicament is selected for local delivery (Col 9 line 18)

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crocker as applied to claim 1 above, and further in view of BERRIGAN (US # 5,871,478).

Crocker teaches the limitations of claim 1 as above, but does not teach the use of a relief valve in the reservoir.

Berrigan teaches the use of a relief valve (20) in the reservoir of a drug delivery means comprising similar components a Crocker (i.e. a reservoir (18) and perforator (21) in fluid communication (Fig 1)).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine the medicament delivery system of Crocker with the relief valve of Berrigan in order to prevent unwanted buildup in the reservoir of the delivery system. (See Claim 15)

8. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crocker as applied to claim 1 above, and further in view of CLARK (US #3,853,125).

Crocker teaches the limitations of claim 1 as above, but does not teach the use of a gas source to supplement the inertia utilized to deliver the medicament.

Clark teaches the use of a gas source (Col 1 lines 9-13) in the reservoir of a drug delivery means comprising similar components a Crocker (i.e. a reservoir (16) and perforator (28) in fluid communication (Fig 1)).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine the medicament delivery system of Crocker with the gas pressure source of Clark in order to deliver the medicament at high pressure (Clark Abstract)

9. Claims 23- 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crocker as applied to claim 1 above, and further in view of DELLY (US #5,993,412)

Crocker teaches the limitations of claim 1 as above, but does not teach the use of a skin position sensor. The skin position sensor, in this reference, also determines the position of the perforator by providing actuating means as to whether or not the injector is in an appropriate position for the needle to be exposed or not.

Delly teaches the use of a skin-positioning impedance (electronic) sensor (10) in a drug delivery means comprising similar components a Crocker

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine the medicament delivery system of Crocker with the skin-positioning sensor of Delly in order to "prevent inadvertent or other discharge of the apparatus when the apparatus is not properly positioned against the skin" (Col 9 lines 10-27).

10. Claims 29-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crocker.

Crocker teaches the limitations of claims 1 and 28 as above, but does not provide specific details as to the type of medicaments to be delivered by his injection device. Crocker discloses (Col 1 lines 5-10) "This invention relates to improvements in devices for delivery of substances such as drugs, vaccines, fluorescent or magnetic material, and dyes into a surface, such as the skin of a human being, animal or other organic matter. The substance may be a solution, particulate fluid, or a paste, for example." As disclosed, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the injection device for various medical treatments requiring the injection of medicaments into the body.

11. Claim 21 rejected under 35 U.S.C. 103(a) as being unpatentable over Crocker.

Crocker discloses the limitations of claim 1, but does not expressly disclose the use of a plurality of reservoirs. Crocker does disclose the use of one reservoir and one membrane, the membrane being used a reservoir, which in combination the Examiner considers to be a "plurality of reservoirs." Moreover, it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St Regis Paper Co. v. Bemis Co.* 193 USPQ 8.

12. Claim 12 rejected under 35 U.S.C. 103(a) as being unpatentable over Crocker.

Crocker discloses the claimed invention except for the limitation that the reservoir has a volume of 10 microliters to 50 milliliters. It has been an obvious matter of design choice to select a reservoir within this volume range, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 7:00-3:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM



KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

